

2018

N2 Strategic Plan

(2018-2022)



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EXECUTIVE SUMMARY

The Approach

This is N2's second Strategic Plan that aims to provide five years of guidance (2018-2022). As a membership-based and -driven organization, N2 has incorporated the voices and feedback of member stakeholders in to its strategic direction from the membership survey conducted in early 2017, one on one consultations with member stakeholders held over the course of 2017, and from Committee Chairs, members, and attendees of the 2018 annual conference.

The Aspiration

After a decade in operation, N2 is at a place in which it has well-established operations within the Canadian clinical research environment and is poised to continue to grow and exert influence. In addition to continuing to build tools and resources that enable its members to conduct high quality clinical research, N2 aspires to be a truly collective national voice for the clinical research community in Canada.

Strategic Priorities for 2018-2022

The strategic priorities of N2 for 2018-2022 are:



Evaluation

It is critical for N2 to benchmark its achievements against this Strategic Plan; demonstrating to membership its accomplishments and its ability to deliver. The Strategic Plan will be accompanied by an Operations Plan (that will be updated annually), against which an evaluative framework will be laid.

PREAMBLE

Need for the Plan

As the Canadian clinical research environment continues to evolve, N2 must develop a strategic plan that will meet our members' needs with respect to this complex and changing environment. Since N2's first strategic plan, our organization has grown, in numbers and diversity in our membership base and has moved from having completely volunteer organization to having select staff positions.

With N2 representing the voice of 120 clinical research and trial organizations and growing, it is poised to continue to advance their abilities to conduct high quality clinical research and clinical trials. As such, this Strategic Plan will set the key priorities for our work in the coming 5 years, inspiring our members and community to: continue to grow; become more unified as a collective national voice of the clinical research and trials community; and, raise the bar on the quality and safety initiatives that guide our work.

Approach to the Task

This is N2's second Strategic Plan that aims to provide five years of guidance (2018-2022). As a membership-based and -driven organization, N2 has incorporated the voices and feedback of member stakeholders in to its strategic direction from the membership survey conducted in early 2017, one on one consultations with member stakeholders held over the course of 2017, and from Committee Chairs, members, and attendees of the 2018 annual conference.

Organization of the Plan

This Strategic Plan is laid out starting with a reminder of N2's vision, mission and strategic priorities for 2018-2022 that will be discussed in further detail later. The discussion also includes: how the clinical research landscape has changed since our first strategic plan was written in 2012; and, information about N2's strategic partners and N2's stakeholders. A strengths, weaknesses, opportunities and threats analysis are undertaken to help establish a basis for this Strategic Plan. Lastly, the strategic priorities for 2018-2022 are described. An evaluation of this Strategic Plan is described very briefly as it will be closely tied to an annually-updated accompanying Operational Plan.

ABOUT N2

Vision

Canada's alliance for excellence in clinical research.

Mission

To enable and enhance clinical research capability and capacity in Canada.

Strategic Priorities for 2018-2022

1. Position N2 as a national voice for clinical research in Canada;
2. Shepherd a national clinical research alliance; and,
3. Advocate for peak performance and quality outcomes in clinical research.

CLINICAL RESEARCH LANDSCAPE

How the Landscape Continues to Evolve

The Canadian research landscape continues to evolve and while the landscape remains a mix of organizations (as reflected by N2 membership) that includes government organizations, non-governmental agencies, academic institutions, professional associations and pharmaceutical, biotechnology and device companies, and others, new organizations and associated initiatives have also emerged. Some of these organizations include: the Canadian Clinical Trials Coordinating Centre (CCTCC) and the Strategy for Patient-Oriented Research (SPOR) Support Units in each province/region that are co-supported by provincial funding. Additionally, clinical research-related organizations that are US-based and without a significant presence to date in Canada, have been signaling a desire to conduct activities in Canada.

Whereas N2's mandate does not overlap with these organizations or initiatives, there are complementary opportunities. For example, N2 is represented on the CCTCC National Advisory Committee, and information about N2 has been provided or discussions about N2 have occurred with some of the SPOR Support Units. In BC and Saskatchewan, the provincial SPOR Support Units have provided the resources for provincial N2 memberships.

While clinical research operations remain complex, a number of initiatives and organizations across the country have been aiming at and making progress towards streamlining various clinical research processes. Some examples of such initiatives include: streamlining the research ethics review process (in BC, Alberta, Ontario, Quebec); roll out of the permission to contact program (in BC and Ontario); creation of a national clinical trials asset map (hosted by CCTCC); streamlining contract negotiations (CCTCC); and, Fair Market Value and budget negotiations (hosted by CCTCC), and a number of provincial initiatives (AB, ON). With respect to these types of initiatives, N2 has and will continue to generally act as a consultant and/or convener, bringing together its members to learn more about these efforts and initiatives at stakeholder meetings and webinars, as well as leveraging these initiatives where possible. Various members of N2 have been involved in these initiatives in different capacities as well.

Strategic Partners

N2 has developed strategic partnerships with a number of organizations through formal agreements (Memoranda of Understanding or Partnership agreements). Through these formal agreements, N2 is publicly recognizing a relationship with organizations and signaling more formally how efforts have been undertaken to work together. These organizations include:

- HealthCareCAN
- The Canadian Association of Research Administrators (CARA)
- The Canadian Cancer Clinical Trials Network (3CTN)
- The CITI Program
- The Metrics Champion Consortium (MCC)
- Life Sciences Ontario (LSO).

These formal agreements lay the foundation to build N2's scope of influence and national voice and to create resources and tools of mutual gain. N2 recognizes that there are other organizations that may wish to formally partner, and exploration of such partnerships and opportunities continues given the positive input from members with respect to such discussions.

Stakeholders

N2 has identified a broad range of clinical research professionals and organizations as its stakeholders. These stakeholders are categorized here by their interaction with N2.

These stakeholder categories can include both member organizations and external parties. They are:

1. **Site Personnel** (Clinical research coordinators, clinical research nurses, investigators);
2. **Academic Research Leaders** (Vice Presidents of Research Institutes, SPOR Support Units, etc.);
3. **Industry and Sponsor Leaders** (Pharmaceutical, biotechnology, device and contract research organizations);
4. **Regulators** (Government regulatory agencies, provincial health authorities);
5. **Funders** (National granting agencies, health charities) and;
6. **Patients** (“anyone who has personally lived the experience of a health issue as well as their informal caregivers, including family and friends”¹).

N2’s efforts have primarily focused on the clinical research professionals and research organizations as members for which its activities, resources and tools are developed. Recently this has expanded to include a number of patient organizations and health charities, through the development of informal relationships and more to inform these organizations of public-facing tools N2 has developed.

N2 continues to welcome all stakeholders in the clinical research and trials space as members, recognizing that its resources and tools will be of most value to organizations that are directly involved in carrying out clinical research and clinical trials.

¹ <http://www.cihr-irsc.gc.ca/e/49232.html>

SWOT ANALYSIS

Based on the N2 membership survey and one on one conversations with member organization stakeholders, a SWOT analysis is provided here.

STRENGTHS

- A comprehensive inventory of assets (resources and tools) that meet current regulatory requirements and enhance high quality clinical research in Canada (such as standard operating procedures, CITI training, Health Canada Guidance Documents/Inspection Information)
- An established network to support exchange of ideas, networking, and other opportunities that promote collaboration and a unified voice for clinical research (for example, the Initiative to Streamline Clinical Trials).
- Breadth of membership is nationally representative and reflective of all types of organizations that conduct clinical research.
- A decade-long track record of providing a national voice, and high-quality resources and tools in the clinical research space.

WEAKNESSES

- Varying levels of communications penetration within membership organizations, as reflected by different levels of member stakeholder awareness of N2's resources and tools.
- Lack of awareness of N2 amongst non-member organizations.
- Lack of coordinated messaging and advocacy efforts to date.
- Limited capacity due to being driven primarily by volunteers.

OPPORTUNITIES

- Improve member and non-member awareness of N2 and its initiatives.
- Create synergies or consolidate resources with external partner / stakeholder organization (e.g. for educational tools).
- Building public awareness of clinical research.
- Elasticity of market space to expand membership numbers and type
- Elasticity of market to define new tools and resources offered by N2
- Market need for a connector role / advocate between member organizations and other stakeholders.
- N2's current network to promote N2.
- Need for a consistent forum for discussion, input and feedback from members to Health Canada.

THREATS

- Maintaining financial stability and reserves in the face of increasing costs.
- Maintaining diverse national representation at the Board of Directors level.
- Dilution of the N2 differentiator to other stakeholders.

STRATEGIC PRIORITIES AND OBJECTIVES

Strategic Priority: Position N2 as a National Voice for Clinical Research in Canada

N2 is a collection of more than 120-member organization voices that can advocate with respect to issues affecting or influencing clinical research in Canada. N2 is invested in ensuring that clinical research continues to be conducted in Canada and that global operations see Canada as a source of high quality and high integrity clinical research.

Positioning N2 as a national voice is important to strengthen N2's ability to be seen as the 'go to' representative of numerous diverse stakeholders within the Canadian clinical research landscape. N2's current initiatives related to the Initiative to Streamline Clinical Trials, raising awareness (the It Starts With Me and Ask Me campaigns), and its efforts to build research capacity all demonstrate its efforts to facilitate this national voice. The individuals who are actively engaged in N2 represent both operational and strategic perspectives of clinical research organizations and as such are well-versed with respect to all types of challenges faced by these organizations. Access to these opinions, views and expertise allows N2 to provide a well-informed and well-founded perspective during discussions with regulatory agencies, funding agencies, etc. N2's representation ensures a voice that represents many facets of clinical research – from operational to strategic.

Objectives:

- **Objective 1.1:** Develop a communications strategy that effectively engages and informs key stakeholders.
- **Objective 1.2:** Influence strategic clinical research initiatives at the national and international levels.
- **Objective 1.3:** Advocate with respect to policy, regulations, etc.

Strategic Priority: Shepherd a National Clinical Research Alliance

Given the current conservative climate with respect to all types of research resources, fostering collaboration among stakeholder groups remains a cornerstone for N2. Leveraging initiatives amongst its membership (regionally, provincially, and nationally) allows N2 to convene its stakeholders to make the best use of limited resources and also encourages an innovative spirit and approach to deliver creative solutions.

Creating resources for N2's membership via sharing know-how and pooling of resources allows N2 members to utilize their own limited resources more appropriately. Additional efforts will be undertaken by N2 to better penetrate its membership and increase the effectiveness and use of these resources. These efforts will further strengthen Canada's clinical research enterprise and also help ensure consistency and high quality amongst member sites.

Objectives:

- **Objective 2.1:** Host regional meetings to bring together N2 members and non-members so that collaborations can be fostered and many voices are heard.
- **Objective 2.2:** Continue to build and execute on the Initiative to Streamline Clinical Trials (ISCT) with Health Canada.

Strategic Priority: Advocate for Peak Performance and Quality Outcomes in Clinical Research

N2 is helping ensure its members' success their efforts to conduct high quality research with integrity, efficiency and continuous quality improvement through access to and facilitated use of quality tools, resources and programs. These bilingual tools and resources help N2 members meet the regulatory requirements of a number of agencies to support global clinical research efforts, and maintain up to date education and skills, of the highest standards. Well-equipped and educated clinical research professionals are key to attracting additional clinical research efforts to Canada, and ultimately benefit Canada's population and healthcare system.

Objectives:

- **Objective 3.1:** Develop and maintain standard operating procedures.
- **Objective 3.2:** Develop and deliver clinical education content.
- **Objective 3.3:** Develop and offer a quality management program.
- **Objective 3.4:** Facilitate national recruitment efforts.

EVALUATION

An Operational Plan that will be updated annually is included as the Appendix to this Strategic Plan. The Operational Plan includes actions and outcomes developed to achieve each Strategic Priority, along with who or which Committee will be responsible for these. Evaluation of the organization's progress against this Operational Plan will provide measurement of this Strategic Plan.

APPENDIX

The Writing Team

The team that wrote this Strategic Plan included N2’s Board of Directors, the Business Development Specialist, the Communications Specialist, and the Administrative Officer/Project Assistant.

Operational Plan

VISION	Canada’s alliance for excellence in clinical research		
MISSION	<i>To enable and enhance research capability and capacity in Canada</i>		
STRATEGIC PRIORITIES	 Position N2 as a national voice for clinical research in Canada	 Shepherd a national clinical research alliance	 Advocate for peak performance and quality outcomes in clinical research
KEY OBJECTIVES	<ul style="list-style-type: none"> • Develop a communications strategy that effectively engages and informs key stakeholders. • Influence strategic clinical research initiatives at the national and international levels. • Advocate with respect to policy, regulations, etc. 	<ul style="list-style-type: none"> • Host regional meetings to bring together N2 members and non-members so that collaborations can be fostered and many voices are heard. • Continue to build and execute on the Initiative to Streamline Clinical Trials (ISCT) with Health Canada. 	<ul style="list-style-type: none"> • Develop and maintain standard operating procedures. • Develop and deliver clinical education content. • Develop and offer a quality management program. • Facilitate national recruitment efforts.